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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,927	11/17/2000	Leonard I. Zon	1242.1035-002	6132

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EXAMINER

WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/21/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/715,927

Applicant(s)

ZON ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52,54-63 and 65-133 is/are pending in the application.
- 4a) Of the above claim(s) 1-45 and 73-133 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46,52,54-63 and 65-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Amendment filed 1/7/03 (Paper No. 14) has been entered into the record. Claims 53 and 64 are cancelled. Claims 46-52, 54-63 and 65-72 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

URLs

The objection to the specification because it contains browser-executable code, as set forth at p. 5 of the previous Office Action (Paper No. 12, 7/31/02), is *withdrawn*. Applicants have amended the Specification to remove all URL's (Paper 14, 2/5/03).

Maintained Objections and/or Rejections

35 USC § 112, first paragraph – scope of enablement.

Claims 46-52, 54-63 and 65-72 are rejected under 35 U.S.C. 112, first paragraph, as set forth at pp. 5-10 of the previous Office Action (Paper No. 9, 7/3/01), because the specification, while being enabling for the polynucleotide of SEQ ID NO: 1, encoding a Zebrafish iron

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transporter, does not reasonably provide enablement for polynucleotide(s) as recited in Claims 46-52, 54-63 and 65-72.

The claims are directed to a polynucleotide encoding a transporter polypeptide. The specification discloses a Zebrafish iron transporter and uses it to measure iron flux across *Xenopus* oocytes transfected with the polynucleotide(s) encoding the transporter. The specification also discloses methods for recombinantly expressing the disclosed transporter polypeptides. The specification further discloses human and mouse polypeptides that appear to have 9-12 transmembrane domains -typical of a transporter- and 82-89% similarity to the Zebrafish iron transporter.

Applicant's discussion (Paper 14, 7 January 2003, p.7, p.8, etc) concerning scope of enablement of claims 46-52, 54-63 and 65-72, center on two main arguments: Firstly, the Applicant argues, the claims point to the iron transporter *nucleic acid*, not the polypeptide specifically and that it is a matter of routine experimentation to make and use the polynucleotides specified in the claims. The second set of arguments essentially states that the claims need not "encode a protein that functions in a specific way" (Paper 14, 7 January 2003, p.7).

Applicant's arguments have been fully considered but are not found to be persuasive. The rejection (See Paper 12, 3 July 2002) centers on the lack of guidance regarding specific activity of SEQ ID NO: 5 and/or SEQ ID NO: 6 and variants, and the lack of working examples to all possible claimed variants of the polynucleotides encoding SEQ ID NO: 6. The specification is enabling for the transporter encoded by SEQ ID NO: 1, not for variants of that transporter polypeptide. The Applicant argues that one skilled in the art would know how to make and use the claimed polynucleotide(s), muteins and fragments. However, specific

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activities of the protein of SEQ ID NO: 5 and fragments comprising are not disclosed. Since there is no discussion in the instant case as to which particular amino acids are necessary to maintain the functional characteristics of the disclosed polypeptides, the polynucleotides encoding the fragments are not useful. Furthermore, without adequate guidance from the instant Specification, the quantity of experimentation necessary to make and use the entire scope of the polypeptides and polynucleotides specified in Claims 46-52, 54-63 and 65-72 is enormous. The specification presents guidance on how to obtain the polynucleotide of SEQ ID NO: 5, and recombinantly produce the iron transporter of SEQ ID NO: 6, techniques that are indeed routine in the art. It also teaches iron flux experiments in which the Zebrafish iron transporter of SEQ ID NO: 6 can be used to transport iron across the plasma membranes of transfected cells. However, it does not teach how to make all polynucleotides encompassed by Claims 46-52, 54-63 and 65-72 which necessarily would *retain the function* of the Zebrafish iron transporter.

The second set of arguments put forth (Paper 14, 7 January 2003, pp 6-8) is related to the first in that the Applicant argues that the Specification need not teach *how to use* the claimed polypeptide(s). The Applicant states that the claims need not “encode a protein that functions in a specific way” (Paper 14, 7 January 2003, p.7). And, on page 8, paragraph 2, Applicant states: “The examiner seeks an activity for polypeptide fragments encoded by the isolated nucleic acids, vectors and cultured cells of the claims. It is not necessary for Applicants to describe such an activity, as polypeptide fragments are not the subject of Claims 49, 50, 58, 63, 64 and 68. Making the invention should should present no difficulty to one of ordinary skill in the art.” The

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Applicant then refers to the uses for the claimed polynucleotides as listed in the Specification (p. 45).

Applicant's arguments have been fully considered but are not found to be persuasive. 35 USC § 112, first paragraph, makes clear that the inventor must teach how to use the invention. The previous Office Action (Paper 12, 3 July 2002) centered on the lack of guidance regarding uses for SEQ ID NO: 5 and/or SEQ ID NO: 6 and variants, and the lack of working examples that used variants of the polynucleotides encoding SEQ ID NO: 6, as embraced by the claims. The Applicant argues that one skilled in the art would know how to make, and therefore use, the claimed polynucleotide(s), muteins and fragments. However, *specific* activities (e.g., unique to the proteins/nucleic acids) of SEQ ID NO: 5/6 and the other claimed embodiments are not disclosed. Similarly, concerning the fragments of SEQ ID NO: 6 or 5, since there is no discussion in the instant case as to which particular amino acids are necessary to maintain the functional characteristics of the disclosed polypeptides, the polynucleotides encoding the fragments are not useful. Likewise, experiments that demonstrate that the human transporter of SEQ ID NO: 6 has a function very similar or the same as that of the Zebrafish transporter are not disclosed.

The Applicant argues in the reply of 7 January 2003 (Paper No. 14) that homology of the human iron transporter of SEQ ID NO: 6 to the Zebrafish iron transporter of SEQ ID NO: 2 is sufficient to impart function to the human transporter. However, as discussed in the previous Office Action (Paper 12, 3 July 2002, p. 7) in the receptor art, homology is insufficient for describing a protein unless accompanied by assays of the protein's function. This is evident by examples of numerous receptors bearing high homology, yet disparate functions. For example,

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Gal2 and *Hxt4* are two structurally closely-related proteins, which transport different substrates (Bisson et al., 1993, Crit. Rev. Biochem. Mol. Biol., 28: 259). Likewise, Liang et al. found that single amino acid substitutions in yeast glucose transporters can change substrate selectivity (Liang, H., 1998, Mol. Cell. Biol. 18: 926). These examples and others illustrate that it is not predictable as to which amino acids are necessary to maintain the functional characteristics of a protein, and that even very high homology is not necessarily predictive of function.

In support of a function for the Human iron transporter of SEQ ID NO: 6, Applicants have enclosed with the Response of 7 January 2003 (Paper 14) a paper showing a human ferroportin gene that encodes a transporter with iron transport function (Montosi, et al, 2001, J. Clin. Invest. 108: 619-623). Data showing that SLC11A3 of the Montosi paper is identical to the gene encoding the human iron transporter of the instant Application and an Information Disclosure Statement documenting the Montosi paper may be persuasive in establishing a function for the claimed polynucleotide(s) encoding the human iron transporter peptide.

35 USC § 102-Prior Art

The rejection of Claims 55, 58 and 68 under 35 U.S.C. 102(b), as set forth at pages 10-11 of the previous Office Action (Paper 12, 7/31/02), is *maintained*.

Applicants argue that the reference (Fujiwara, et al, 1995, Accession No. D63209) does not disclose all elements of the claims. However, Claims 55, 58 and 68 read on a polynucleotide

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“portion”, which can be any length, and uses “comprising” language that encompasses all polynucleotide *portions* found in the earlier reference.

Conclusion:


Claims 46-52, 54-63 and 65-72 are rejected for the reasons cited above.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623. Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

4/4/03


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